UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,314	01/26/2001	Graham D. Marshall	32020-8001US1	7648

25096 7590 07/08/2003

PERKINS COIE LLP
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	5

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,314	MARSHALL ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *32-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-31, drawn to a flow-based analysis system connectable to a sample source, classified in class 422, subclass 81.

   II. Claims 32-42, drawn to a method of analyzing a plurality of samples using sequential analysis, classified in class 436, subclass 43.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method may be practiced by another apparatus, for the method does not require the particulars of the claimed device such as the controller as claimed in the structure of the apparatus claims.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Robert G. Woolston on June 10, 2003 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-31. Affirmation of this election must be made by applicant in replying to this Office action. Claims 32-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 4, 15, 16, 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims contain the terms "disposable" or "re-usable". The terms do not provide any further structure to the device. It is one's own choice to decide to discard or re-use a device. However the examiner believes that applicant intends to express that

the cartridges are structurally capable of being readily removed or replaced, which implies that they have a detachable connection to the system.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

11. Claims 1-7, 10, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Uffenheimer US 5,558,838.

Uffenheimer discloses a sample preparation apparatus which includes a pair of valves. A first valve selectively communicates a sample tube with a vent/aspiration valve, or alternatively communicates a diluent pump with a reaction tube. By moving the first valve, one may selectively relieve a vacuum within a sample tube, aspirate a sample from the tube, or alternatively may drive a diluent and a sample into the reaction tube. The second valve is a vent/aspiration valve which selectively communicates the first valve to two distinct systems. A first system vents a vacuum in the sample tube, and a second system aspirates a sample from the sample tube. The second valve is actuated to initially relieve any vacuum in the sample tube, and is then actuated to connect the aspiration system to the sample tube to begin to withdraw of a sample from the sample tube. At the same time, the diluent pump is filled. The shear valve is then moved to communicate the diluent pump to the reaction tube. The diluent pump is actuated to drive a diluent and a sample slug into the reaction tube, which preferably contains a predispensed reagent. This system simplifies the valving structure over the prior art systems. In addition, a unique rinse system provides a rinse solution to the

outer periphery of the needle, while the needle is connected to a source of suction to withdraw the rinse fluid. Finally, a unique structure for holding and properly positioning the reaction tube provides a control signal indicating that a reaction tube is received in the reaction tube structure. If no reaction tube is sensed, a **controller** deactivates the system such that no fluids are dispensed by the system.

A sample preparation apparatus 20 is illustrated in FIG. 1 including a control panel 22 for controlling the operation of the system. A tube guide 24 (cartridge support with alignment member) receives a closed sample tube 26 (reagent cartridge with a reservoir) including closure 28 (penetrable septa). Tube guide 24 guides sample tube 26 downwardly onto a **needle** 30 which punctures the closure 28. As will be explained below, any vacuum in the tube will be vented at that time. The sample may then be aspirated from the sample tube 26 and delivered to a reaction tube 32. A diluent pump 34 (fluid propulsion) communicates to the reaction tube 32 through a shear valve 36. Preferably, reaction tube 32 contains a predispensed reagent.

As shown in FIG. 2A, **needle** 30 has punctured the closure 28 and line 41 communicates with the interior of sample tube 26 (reagent cartridge) through needle 30. As shown in FIGS. 2A, and 2B, a rinse line 42 communicates with a chamber 44 at the outer periphery of the needle 30. Rinse line 42 is connected to a rinse fluid 46 through a pump 48. As will be explained below, after a sample is aspirated from sample tube 26, needle 30 is retracted and rinse fluid is delivered to chamber 44 to clean needle 30.

As also shown, a sample loop or passage 50 extends through shear valve 36. In addition, a groove 52 connects a diluent fluid 54 through a line 56 to a line 58 leading to diluent pump 34.

As shown in FIG. 2A, shear valve 36 (a stream selection device) is in a position where passage 50 communicates line 41 (tubing) from needle 30 to a passage 60. Passage 60 will be termed a "valve passage" for purposes of this application as it connects the two main valves of this invention. Passage 60 passes through conductivity **detector** 61, and communicates with a vent/aspiration valve 62 having a passage 64. In the position shown in FIG. 2A, passage 64 communicates passage 60 to a passage 66 leading to a check valve 68 which is in turn connected to atmosphere at 70. A conduit or line 72 is selectively communicated with passage 64 to communicate a pump 74 and waste reservoir 76 to line 60. In a second position of shear valve 36, a passage 59 is communicated through shear valve 36 to the diluent pump 34 to send a sample and diluent to the reaction tube 32, as will be explained below.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uffenheimer US 5,558,838 as applied to claims 1-7, 10, 12 above, and further in view of Tremmel et al. US 5,171,538 or in the alternative Mack et al. US 6,149,872.

Uffenheimer does not disclose that the reagent cartridge contains a lyophilized reagent.

Tremmel discloses a reagent supply system for a medical anlytical instrument includes a reagent space provided on the instrument and reagent vessels which are received in the reagent space. In the reagent space there is provided at least one

reagent vessel compartment with a bottom, lateral guide elements, and a top guiding element, as well as a front stop. The instrument contains a fluid communication system for connection with a reagent vessel situated in the reagent vessel compartment. On the end face of the reagent vessel compartment is disposed a hollow needle near the bottom surface thereof and extending in a direction which is parallel to the bottom surface. The reagent vessel has on its front wall facing the end face a pierceable seal with a pierceable elastic stopper.

Mack et al. dislcose a modular reagent cartridge (10) which includes a plurality of reagent containers (12 to 18) directly interconnected by integrally formed coupling devices (22). The connection is brought about by form-locking rail guides. The invention relates to a reagent cartridge for the supply of ready-to-use, biochemical reagents in liquid form, whose purpose is to enable a simple loading into and use in a fully automatic analyzer.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that a cartridge may also be used to supply a reagent to the system of Uffenheimer.

16. Claims 8, 13-22, 24-29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uffenheimer US 5,558,838 as applied to claims 1-7, 10, 12 above, and further in view of Dubus US 6,054,326 and further in view of Mack et al.

Uffenheimer does not disclose a reagent cartridge having a plurality of reagent reservoirs.

Dubus discloses a fluid testing and analysing device and a method therefor are described. The device includes, from its base up and in its upstanding configuration, a tube-holder (A) for receiving at least one partially or totally transparent tube (1) so that one wall or part of a wall thereof is visible; one or more tubes (1) forming a closed testing and observation chamber, closure means (4) for each tube, with a needle (3) extending therethrough and a flange (5), surrounding the needle, of smaller diameter than the closure means; a substantially vertical raised portion forming peripheral and/or internal walls surrounding the needles (3) and advantageously higher than the distance by which the needles project above the closure means (4); and, optionally, perforatable sheathes (11) placed on the portion outside the closed chamber (1). The device is particularly useful for human and animal biology applications.

Mack et al. dislcose a modular reagent cartridge (10) which includes a plurality of reagent containers (12 to 18) directly interconnected by integrally formed coupling devices (22). The connection is brought about by form-locking rail guides. The invention relates to a reagent cartridge for the supply of ready-to-use, biochemical reagents in liquid form, whose purpose is to enable a simple loading into and use in a fully automatic analyzer.

The modular reagent cartridge 10, which is depicted in FIG. 1, is constructed by connecting directly to each other several reagent vessels 12, 14, 16 and 18 by means of coupling devices, moulded-on as one piece. In so doing, the reagent vessels 12, 14 and 16 are designed the same and comprise an essentially square-shaped vessel, which is sealed with a rubber disk 21, which is made of silicone, is slit, enables the filling of the

reagent vessels in one special manufacturing step, and enables automatic removal of the aliquots in reagent positions in the analyzer. The type and shape of the slit, which can be designed in the shape of a cross, star or straight line, is preferably constructed in such a manner that it seals again following extraction of the filling mandrel of a filling machine or pipetting needle of the analyzer.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the supply system of Uffenheimer to incorporate a muli-accessible cartridge support (as taught by Dubus) and a modular reagent cartridge as taught by Mack et al. in order to allow for different combinations of reagents to be supplied to the system.

17. Claims 9, 23, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uffenheimer in view of Dubus and Mack et al. as applied to claims 8, 13-22, 24-29 and 30 above, and further in view of Laska et al. US 5,104,808.

Uffenheimer in view of Dubus and Mack et al. do not disclose a device in which the reagent cartridge includes a machine readable identifier with information.

Laska et al. disclose an apparatus for effecting a plurality of assays on a plurality of samples in an automatic analytical device. The device includes a wand type barcode reader and the reagent cartridge. Each reagent cartridge 52 has a barcode label (not shown) which is read by a wand type barcode reader 16. The information on the label may also be entered via the keyboard 14 in lieu of the barcode reader mechanism. Each reagent cartridge 52 preferably is a multi-compartmented container.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the modified device of Uffenheimer to incorporate a barcode system as taught by Laska to identify and the reagent cartridges.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Doktycz et al., Unno et al., Dubrow et al., Maiefski et al., Markelov et al., Afeyan et al., Sklar et al., Fukunaga, Lewis et al, Kaltenbach et al., Godec et al., Brigham-Burke et al., Sanuki, Kumar et al., Hupe et al., Beckman et al., and Chen disclose liquid transfer systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Jill Warden
Supervisory Patent Examiner
Technology Center 1700

brg
July 2, 2003